ALASKA MEDICAID
PHARMACY AND THERAPEUTICS COMMITTEE

Location of Meeting
4730 Business Park Blvd., Suite 34, Building H, Anchorage, Alaska

MINUTES OF
November 21, 2003
8:00 a.m.

Committee Members Present:
Terry K. Babb
Michael Boothe
Heidi Brainerd
Richard E. Brodsky
Kelly C. Conright
Traci Gale (telephonic)
Charlene Hampton
Arthur S. Hansen
R. Duane Hopson
Diane Liljegren (telephonic)
Ronald J. Miller
Gregory R. Polston (telephonic)
Richard C. Reem
Robert D. Skala
Janice L. Stables
George Stransky
Alexander H. vonHafften
Trish D. White (telephonic)

Committee Members Absent:
John T. Duddy
Nathaniel Haddock
Michael C. Norman
Mike Orms
George S. Rhyneer
Robert H. Carlson

Others Present:
Dave Campana
Sandy Kapur
Lisa Simoro (staff)

I. CALL TO ORDER:

David Campana called the meeting to order at 8:00 a.m.

II. ROLL CALL:

The roll call was taken. The above noted members were present.

III. PUBLIC COMMENTS:

David Campana reviewed the guidelines for the public comments.

Dr. Randy Beckner, regional medical scientist with Glaxco Smith-Kline, discussed Carvedilol (Coreg). Coreg is a broad spectrum adrenergic blocking agent. Coreg is FDA approved in heart failure in post-MI patients with left ventricular dysfunction as well as hypertension. It is the only adrenergic blocker that has FDA approval for mild, moderate and severe heart failure and the only beta-blocker that has been demonstrated in post-MI patients with LVD to reduce mortality by 25%. Coreg has the greatest block aide of adrenergic receptors hitting both beta-1, beta-2 and alpha receptors that are adversely affected in heart failure patients. It is the only adrenergic blocker that has a dose response randomized trial published in the medical literature. Compared to other adrenergic blockers, it has the greatest improvement in left ventricular ejection fractions in head-to-head comparative trials. The uniqueness of Coreg is partially related to its alpha block aide. The metabolic side effects and aspects show either neutral or improvements in glycemic indices compared to Atenolol and Metoprolol, as well as improvement in lipid parameters compared to beta-1 selective agents. A landmark trial was published three to four months ago comparing Carvedilol to Metoprolol demonstrating a 17% reduction in mortality and an increase in longevity of 1.5 years over a five year period without an increase in hospitalizations, so quality of life improvements were demonstrated in the clinical trial. Several cost analyses have been published demonstrating that Coreg decreases hospitalizations by 25 to 30%. A claims comparison of Metoprolol versus Coreg demonstrates significant cost reductions in hospitalizations with Coreg. There are many clinic publications supporting the use of Coreg.

In response to Robert Skala, Randy Beckner discussed the COMET trial that compared Coreg and Metoprolol Tartrate. The doses that were utilized gave comparable beta and heart rate reductions. Over the five-year period, the heart rate reduction was comparable between the two groups. The blood pressure showed between a 3 and a 4-milimeter drop in blood pressure of Carvedilol versus Metoprolol. Related to that was a 67% reduction in strokes, which is probably related to the difference in blood pressure. The COMET trial also demonstrated a 22% reduction in the onset of new type-2 diabetes. It was not a comparative trial of Toprol XL versus Carvedilol. At the time the trial was initiated in 1996, the sustained release formulation was not on the market. When Merit HF was published, the investigators tried to obtain this and the competitor was not willing to supply that formulation. This was the only comparative, large trial that we have to date with 1,500 patients in each arm.

Robert Skala asked if they had been able to prove that even small differences in blood pressure had an impact on the end points of strokes and heart attacks. He asked if there was any validity to the claim that furthering the end points with a different medication might produce mitigations in the end points. For instances, by getting comparable blood pressure levels, we might be able to change the comparison values and make more intelligent choices.

Randy Beckner said he did not know the answer as far as blood pressure went. Several trials have demonstrated that a 4-milimeter drop in blood pressure is clinically significant. There is data demonstrating that higher doses of Metoprolol does not provide greater beta-1 block than doses of 100 milligrams. There is a dose response curve as to how much beta-1 block aide we can achieve with any agent.

Dr. Alden Smith, regional scientific director with Norvartis Pharmaceutical, summarized the clinical high points of both Lotrel, a combination ACE inhibitor and calcium channel blocker, and Diovan, their market leading angiotensin and receptor blocker. In hypertensive trials, Valsartan has shown definitive blood pressure reduction equivalent to agents such as Anlodipin, Lisinopril, Anapril and Losartan. When compared to ACEs and calcium channel blockers, Valsartan has superior tolerability as well as a side effect profile comparable to that of placebo. Looking at special populations, Diovan has demonstrated

effectiveness in isolated systolic hypertension as well as in minority populations. Looking at renal dysfunction, Diovan has demonstrated sustained reduction in blood pressure as well as lowering proteinuria in patients with chronic renal failure, as well as demonstrating a reduction of microalbuminuria in normaltensive and hypertensive type 2 diabetics. Based upon the effects of the VAL-HeFT trial, Diovan is the only ARB indicated in the treatment of heart failure in patients that are intolerant to ACE Inhibitors. The summary of the results of the VAL-HeFT trial was a 13% decrease in total morbidity in the total study population. In the subgroup of patients who are not on an ACE inhibitor, we saw decreases of 41% total mortality, 49% decrease in the risk of morbid events, as well as a 57% decrease in the first heart failure hospitalization. An economic analysis that was performed on the VAL-HeFT study resulted in the patient population not taking the ACE Inhibitors. The increase in survival, as well as the decreased hospitalization costs, resulted in savings of $485 per patient per year. There was a claims database analysis conducted comparing Valsartan to Anlodipin and Lisinopril measuring compliance as well as persistence and there was a significant improvement of both of those measures in favor of Valsartan, independent of chronic disease burden. Finally for Valsartan, the most recent news is the VALIENT trial, which is the use of an ARB post-MI. The VALIENT trial demonstrated that Valsartan is the first angiotensin blocker to be as effective as Captopril in reducing all cause mortality and that was a reduction of about 25%. He summarized the statement from the GNC7 guidelines for Lotrel. Multiple drugs may increase the likelihood of achieving the blood pressure goal in a more timely fashion. ACE Inhibitors and calcium channel blockers are both of the components contained in Lotrel and recommended among anti-hypertensive medications. These two agents have positive data supporting their use in compelling indications. These compelling indications include diabetes, heart failure, post-MI patients with high coronary disease risk as well as chronic kidney disease and recurrent stroke prevention. The anticipated uses of Lotrel are to improve control of hypertension and reduce the risk of cardiovascular complications in various patient populations when monotherapy results in suboptimal blood pressure control. Proving hypertension efficacy superior to either of the ingredients in the product alone, this combination has an additive adrenergic effect, which will minimize dose dependent side effects. Lotrel is demonstrated to be more effective in reducing urine albumin secretion than Benazepril alone and has documented efficacy in reducing microalbuminuria when compared to Anlodipin. Lotrel is more significantly effective in reducing both systolic and diastolic blood pressure in patient with hypertension and type 2 diabetes than Anapril 10 milligrams without effecting glycemic control or lipid parameters. A retrospective database analysis of pharmacy claims, looking at Lotrel's use compared to patients who are taking both an ACE inhibitor and a calcium channel blocker separately, showed a significant improvement in medication position ratio equating to about 27 days more compliance per year in favor of Lotrel.

Dr. Eugene Sun, internist and regional director with Merck and Company, felt the committee's decisions were very important and would critically affect the health of many citizens. He reviewed Cozaar and Losartan angiotensin receptor blockers, and Alendronate (Fosamax), a bisphosphonate for osteoporosis. It is important when considering hypertensive agents to differentiate between serigate markers and clinical outcomes. Mercury blood pressure lowering and reduction of microalbuminuria are very important serigate markers to consider when looking at an agent. The reason clinicians treat hypertension is to reduce organ damage and outcomes. Losartan and Cozaar have robust data showing they reduce the risk of stroke when compared to the active comparator, Atenolol. There is also data showing that it decreases the risk for end-stage renal disease. Dialysis and renal transplants are costly items for the Medicaid program in type 2 diabetics with nephropathy. Serigate markers are important clinical measures used by clinicians. Bone mineral density, BMD, increases are very important to track and monitor, but in the end we are looking for reductions in fractures. Vertebra fractures are painful and debilitating, but hip fractures are worse. 25% of the people who suffer hip fractures have a one-year

mortality of 25%. Fosamax is the only FDA approved agent with an explicit reduction in hip fracture incidents.

In response to Robert Skala's reference to the September 20, 2001 article in the New England Journal of Medicine regarding Irbesartan, Dr. Eugene Sun said the results for Irbesartan did not reach statistical significance, especially if you adjusted for the differences in blood pressure between the treatment groups. Both in life trials for stroke and end-stage renal disease reductions, the significance still remained highly significant in favor of Losartan.

In response to Sandy Kapur, Dr. Eugene Sun said he supported the ADA guidelines for type 2 diabetics. ADA was a very well known institution that did not come down on the side of any individual product, which was how they maintained their credibility. He felt it was important to differentiate between serigate markers and actual data showing the hard clinical improvements and benefits.

Margeurite Stetson said she was a volunteer with AARP and served as the state coordinator for advocacy efforts in Alaska. Medicaid prescription costs are escalating inappropriately and must be controlled. AARP supports the preferred drug list. We believe the preferred drug list, with the appropriate consumer protections, will help our state avoid cuts in eligibility and Medicaid benefits and will expand access to affordable drugs. The preferred drug list takes advantage of the pharmaceutical manufacturers' desire to maintain their market share. The drug manufacturers will have the opportunity to retain their market share if they offer sufficient price breaks for prescriptions purchased by Medicaid. Many states with established preferred drug lists have been able to generate additional savings by expanding the size of their purchasing power. Alaska needs to adopt a similar program. When AARP looks at whether a preferred drug list will effect the health and safety of consumers, they look at how the preferred drug list will be structured. The preferred drug list will allow physicians to make exceptions when they deem it in the medical interest of their patients. We do not believe we should pay $100 for a medication if we can get the same therapeutic benefit from a $20 medication, as long as the patient has access to the $100 medication if their physician deems it necessary. We have seen the benefits of good evidence-based pharmacology at the Alaska Pioneer homes. A few years ago the residents, with an average age of 89, used 14 medications each. By 2002, through diligent attention by pharmacists working with the residents and their physicians, they were able to reduce average usage to 7 medications. At this time, they have been able to reduce usage to 4.5 medications each. In addition to reducing overall drug usage, they have also been able to use less expensive prescriptions. The results are healthier pioneers with savings by individuals and the State of Alaska. The PDL Committee will be composed of our best and brightest pharmacists and physicians who are concerned about the health of the Medicaid participants as well as the fiscal health of the Medicaid Program. The preferred drug list will help provide good service based on therapeutic evidence and not the latest marketing gimmicks of pharmaceutical manufacturer. AARP is pleased that Alaska is developing a preferred drug list. This is good medicine and responsible public policy. AARP pledges their efforts in supporting the preferred drug list and its implementation.

In response to Robert Skala, David Campana explained the format for determining overrides of soft and hard edits to the preferred drug list. Physicians would note the medical necessity for the non-preferred drug on the prescription and in the patient's chart. The pharmacist would put an indicator on the prescription indicating that the physician had noted that the non-preferred drug was medically necessary. The physician would not have to obtain a prior authorization, but would only note the medical necessity on the prescription. If the prescription was for a non-preferred drug, but the physician failed to note its

medical necessity, the pharmacist would have to contact the physician to verify whether he wanted the non-preferred drug or the preferred drug.

Robert Skala discussed the effectiveness of a preferred drug list if physicians could still prescribe the non-preferred drugs. David Campana said the committee would determine which drugs would be on the preferred drug list. They hoped to have 90-95% compliance from the providers, which would reduce the budget by forcing competition in the drug classes.

Robert Skala pointed out that a preferred drug list was different than a general set of guidelines and recommendations for the practitioners.

David Campana said guidelines followed multiple drug lists, but the PDL would be a single drug class with specified preferred and non-preferred agents, which would allow them to obtain supplemental rebates and drive down the net cost of the drugs.

The committee discussed the effect of limiting the competitiveness of the drug companies, which could shut down the market for 8 of the 10 drugs and reduce their ability to drive new research. David Campana did not feel Alaska's small market would make much of a difference. Sandy Kapur felt the PDL would decrease PHARMA's ability to manipulate the market or provide inappropriate advertisements. She felt it might actually enhance PHARMA's ability to find better drugs that applied to a wider population. Robert Skala felt they needed competition to encourage innovation and the preferred drug list would limit competition.

Dr. Brasha Hagaw, a scientist from Seattle, reviewed Atacand and Toprol XL. Most of the data for ARBs are in hypertension, nephropathy and heart failure. Atacand has a superiority claim over Cozaar for hypertension from the FDA based on the clinical data. The CHARM study showed a benefit of 40% reduction in new onset of diabetes for patients who used Atacand when patients were intolerant to ACE Inhibitors, or added on top of ACE Inhibitors and beta blockers, to treat heart failure. There is compelling evidence in the ARBs with Atacand that makes it the drug of choice. He discussed beta blockers. Metoprolol, Immediatrolize and Toprol XL are very different. Toprol XL provides 24-hour coverage in controlling the beta-1 receptors, which is important for the patient. Toprol XL is one of the two drugs approved by the FDA in heart failure. He discussed the doses of the various medications. The benefit of Toprol XL in all cause mortality was 39%. Toprol XL has been shown to reduce sudden death at 50% in the MERIT HF study. Death due to heart failure has also seen a similar benefit. Toprol XL has indications for hypertension, stable angina and heart failure with one dose a day. Toprol has a neutral effect of lipid parameters and glucose.

Joe Fuller said PHARMA was not supportive of restricting access to products for Medicaid patients. They felt it was important that the process was fair, open and transparent. Oregon has implemented a PDL and Washington is developing one. It has taken those states years to get as far along as Alaska has gotten in the last few months. PHARMA hoped that the physician/patient relationship would not be jeopardized. Physicians should be given the opportunity to prescribe what they felt was appropriate. Washington and Oregon did two things that Alaska has not done. They developed regulations that went through the rules process, which allowed for an open public process. PHARMA believes that it is important for physicians to be able to write "dispense as written" on the prescription so the patient will get what the physician deems appropriate as done in Oregon and Washington. The medical associations in Oregon and Washington endorsed the PDL, because they knew that if patients fell outside of the parameters, the option was still there for the physician to provide quality care.

David Campana closed the public comment session. We are experiencing growth in our pharmaceutical budget within the Medicaid population. The growth consists of increases in patient load, volume of prescriptions and increases in costs. We hope the preferred drug list will level out the growth in the costs. PHARMA felt that pharmaceuticals had a tremendous cost advantage over other treatments, but a PDL would provide an opportunity for us to decrease the cost increases. We are maintaining access to all currently covered drugs in Medicaid. The physician will be able to make a note on the prescription as to the medical necessity of a drug for the patient. The Pharmacy and Therapeutics Committee can choose to make exceptions for certain groups such as long-term care patients or children. Recommendations on setting the criteria will be presented later in the meeting. The process of obtaining non-preferred drugs is not obtrusive and only requires noting the medical necessity of the drug on the prescription. A regulation went through last year that allowed us to restrict coverage of drugs and we believe the creation of the PDL falls under that regulation. We hope to have buy-in with the program at 90% by the first of the year.

Richard Brodsky felt it would have been helpful if the public comments had been given during the time the particular drug classes were discussed. He asked for clarification on how drugs would be selected for the PDL.

David Campana explained the process. First Health had collected bids on all the drugs within the classes. The committee would determine if the drugs were interchangeable. The generic drugs that had passed their exclusivity period would be on the list. The committee would determine the remainder of the drugs on the list.

The committee discussed the process for issuing prescriptions for non-preferred drugs. Richard Brodsky felt the process for issuing prescriptions for non-preferred drugs should be stronger. He felt the physician should justify his decision to prescribe the non-preferred drug.

In response to Mr. Skala's question on who would review the proposed justifications for prescribing non-preferred drugs, Richard Brodsky said the committee would use the best information they had to develop the PDL and then as new information became available, the committee should review and update the PDL.

In response to Kelly Conright's question on whether physicians would be profiled, David Campana said they would be profiling physicians to determine their rate of compliance with the PDL. Those physicians who were not complying would either be sent a letter or visited by the staff to determine why they were not complying with the PDL.

IV. ANGIOTENSIN II RECEPTOR ANTAGONISTS (ARBs):

Sandy Kapur reviewed the summary information provided by the pharmaceutical manufacturers on their individual agents.

The meeting recessed for 10 minutes so the information could be faxed out to those attending the meeting via teleconference.

Sandy Kapur reviewed the baseline criteria, which was only a suggestion. The committee could choose to be more or less restrictive. The criteria for authorization of non-preferred medications included an allergy to all preferred medications; a contraindication to, or drug-to-drug interaction, with all preferred medications, history of an unacceptable or toxic side effects to all preferred medications or specific FDA approved indications for a non-preferred medications. The criterion must be met prior to approving a non-preferred medication. The requested medication's corresponding generic drug will be used unless it has been attempted first and failed.

In response to Kelly Conright, Sandy Kapur said it would be up to the committee to decide if the history of unacceptable or toxic side effects had to have a proven history in an individual patient or in a specific class such as the elderly. Kelly Conright said she preferred either a combination or class effect in certain groups of people. The criteria should be general and then further refined based on classes or specific medications as indicated.

Sandy Kapur said the first group of agents to be reviewed would be the Angiotensin II Receptor Antagonists (ARBs). The seven ARBs available were Atacand, Avapro, Benicar, Cozaar, Diovan, Micardis, and Teveten. All seven of the drugs are structurally related to Cozaar, with the exception of Teveten, which has its own unique structure and might have its own unique additive mechanisms of action. One of the speakers indicated that Atacand had a FDA labeled indication. Atacand has a superiority claim over Cozaar, however that study was of Atacand at 32 milligrams versus Cozaar at 100 milligrams. The decrease in systolic blood pressure over diastolic blood pressure was 3 millimeters of mercury over 2 millimeters of mercury, which is what gave it the superiority claim. All of the agents are currently available with a combination product with a thiazide diuretic, which makes the synergistic combination hydrochlorathiazide. All seven are FDA labeled for the indication of hypertension. Avapro and Cozaar both have the FDA labeled indication for the treatment of diabetic nephropathy in type 2 diabetic patients, however there are similar studies, CALM for Atacand and MARVEL for Diovan and ongoing studies for Benicar, Micardis and Teveten. The American Diabetes Association has stated that for patients with type 2 diabetic nephropathy with hypertension, ARBs are the initial agents of choice. If the patient cannot tolerate an ARB in type 2 diabetes with diabetic nephropathy then they should be changed to an ACE Inhibitor. However, the ADA did not state one agent to be superior or more effective than any other in that class. Diovan has the unique indication for the treatment of heart failure in patients with class 2 through 4 NYHA heart failure who are intolerant to ACE Inhibitors. Cozaar does have the indication for the treatment of hypertension in patients with CHF. The CHARM trial, which studied Atacand in three populations, showed significant improvement in patients with CHF and will more than likely give Atacand the FDA approval for use in congestive heart failure. There are two very important studies for the ARBs that have come out in the last two months, CHARM and VALIENT. Ultimately, those are two very important and pivotal trials, but they only proved that ARBs are equally effective to ACE Inhibitors in the treatment of congestive heart failure and in patient status post-MI with left ventricular dysfunction. They have not proven superiority over the ACE Inhibitors yet, but they have proven equivalency. When you do have a patient that is intolerant of an ACE Inhibitor, the natural transition to an ARB is clinically sound and clinically founded. Several analysis have shown comparable anti-hypertensive efficacy of all the ARBs, except for Benicar, because it is so new. There are a few differences noted. Cozaar has been noted to have a small urocosuric (ph) effect with a minimal decrease, but it has not been clinically significant. Hypereurosemia (ph) has been noted with Atacand in rare instance. Drug interaction wise, Micardis has a significant drug interaction with Digoxin and can increase levels by about 50%. In the elderly, no adjustment is noted or required. It has always been noted with African Americans that ACEs are slightly less effective. However, with the addition of a thiazide diuretic, equivalency is the same between the African Americans and Caucasians.

In response to Richard Brodsky, Sandy Kapur said they had a general recommendation towards combination products. JNC-7 specifically stated that more and more patients needed two agents at once. With a systolic blood pressure over 20 and diastolic over 10 over goal, it is now recommended to start with two agents. It was not mentioned that JNC-7 states that one of those agents, if not contraindicated, should be a thiazide diuretic. There is not a thiazide diuretic in Lotrel, Lexxel or Tarka, which are the three combination products. When the committee goes over the ACEs and the ARMs, they would recommend the corresponding hydrochlorothiazide product, which is the combination product that would be recommended.

Robert Skala said it was hard to regulate the dosage of combination products, because they came in fixed doses. Many experts shy away from combination products so they can adjust the doses for their patients. However, combination drugs might make it easier for patients to comply rather than having to take several medications.

Richard Brodsky asked if the committee would select several drugs, allow the manufacturers to compete for prices, and then select a final drug for the preferred drug list.

Sandy Kapur said she could provide relative pricing information on what would be the most clinically and net cost effective agents.

The committee discussed how the drug selection process would work. Richard Brodsky wanted to know what other states had done. Robert Skala felt that would be helpful information, especially if they could leveraged their buying power by pooling with other states to further reduce the costs of drugs. Kelly Conright was interested in the rationale the other states used in choosing their preferred drugs. An unidentified female wanted to know what agents the Veterans Administration (VA) had reviewed.

Sandy Kapur said there were some drug classes that the VA had not reviewed. Excerpts from the VA drug class reviews were provided where possible. We did our own research, but we looked at the Oregon and VA drug class reviews, which are considered national guidelines.

In response to Richard Brodsky's question of why the VA drug class reviews were relevant to Medicaid costs in Alaska, Heidi Brainerd said Native American patients that were eligible for health care at Indian Health Service (IHS) related facilities might also be eligible for Medicaid reimbursement from the state. The IHS related medical facilities purchased medications pursuant to the IHS pricing of the VA contract when clinically appropriate and applicable. If a medication is chosen for Medicaid reimbursement, but is not on the VA contract, and its cost is prohibitive, the facility could have the patient receive a prescription to be filled at a private health care facility in the state. There would be reimbursement issues as to how much of the difference the State of Alaska Medicaid would have to make up. Choosing medications on the VA contract is cost effective for the state in some cases.

David Campana said it was cost effective for IHS to purchase medications on the VA contract. The state uses the same formula for all reimbursements. There may be cost advantages for IHS or the Native community if both drug lists are similar. If the lists are not the same then we might have to grant an exception for IHS, which would be up to the committee. IHS reimbursements are advantageous to the state, because we get 100% of the money for all the prescriptions that are dispensed from IHS facilities. It would help our budget if those covered by IHS received their prescriptions through IHS.

In response to David Campana, Heidi Brainerd said purchasing drugs that was not on their formulary was done on a case by case basis. David Campana said it was his understanding that IHS received preferential pricing under the VA contract.

In response to Ronald Miller, David Campana said the VA was reimbursed at the same rate as everyone else with a differential dispensing fee. The health facilities make a profit on their medications, which they use to provide health care for the Native population. Richard Brodsky said the state was reimbursed 100% of the cost of a Native patient whereas a non-Native patient was reimbursed at 60%.

The committee discussed whether the drugs under the ARB class were interchangeable.

Terry Babb noted that the studies that had been discussed had been under controlled environments. He felt the committee should consider compliance for medications that required BID and TID dosing. He did not feel they could say the classes were the same, because some required three doses a day and some only required one dose a day.

David Campana said the committee needed to decide if there was similar outcomes from the drugs and if they can be used interchangeable for 99% of the outcomes. If that is true, then all the drugs should be interchangeable.

Terry Babb discussed the example of diabetic nephropathy and Captopril. In a controlled environment where someone took Captopril every eight hours, it may be more effective, but they needed to consider what would happen if the patient forgot to take the Captopril three times a day over the course of a month. He was not comfortable saying the drugs within a class were interchangeable.

Richard Brodsky said strong opinions that a certain drug should be on the list could be reviewed before the committee voted on it.

David Campana asked if the committee felt there was any single drug that should be the PDL for the ARBs.

In response to an unidentified female, Sandy Kapur said besides looking at the renal clearance, they needed to look at the active metabolites. Diovan had renal clearance of 30% and no active metabolites. If it is metabolized by the liver and there is no active metabolite, there is nothing accumulating even though it is 30% renally cleared. In some cases that would not be a concern if you take everything into consideration. Micardis does not have any active metabolites and 1% renal clearance. Teveten does not have any active metabolites and has 30% renal clearance. Benicar does not have active metabolites and 10% renal clearance. Cozaar does have an active metabolite, but that is only 10% renal clearance. Atacand does have active metabolites and it is predominately renally cleared, so that might be an issue with Atacand. That could be part of the criteria for use or exception.

In response to Sandy Kapur, David Campana felt they needed to come to a conclusion as to whether or not the drugs were interchangeable and then discuss the suggested list. He asked the committee if they felt the ARBs were interchangeable.

Richard Reem noted that they had a list of positive studies, but no information from negative studies.

The committee discussed which drug should be added to the PDL. Janice Stables said Diovan had indications for hypertension and heart failure, which the other drugs did not. It also had the diabetic nephropathy protection and an ongoing study. She felt Diovan should be considered for the list.
Richard Brodsky said there were ongoing studies, but it was believed that there was a class effect for ARBs for treatment of heart failure. He felt there would be work that showed that there was no significant difference.

An unidentified male said the FDA had not defined the term class effects. He felt they should define what they were using as performance measurements when using the term class effects.

Sandy Kapur said the committee needed to determine if any of the drugs in the class would suffice the majority of their needs without inconveniencing the physicians, keeping in mind that there was an override capability to prescribe non-preferred drugs.

In response to Robert Skala's question about physician profiling, Sandy Kapur said they would be doing retrospective physician profiling, but no drugs would be denied when medical necessity was noted. A preferred drug list is not a black and white formulary. All drugs are still available, but there are some drugs on a preferred side and some on a non-preferred side. The visits to the non-conforming physicians could be an educational process for both the physician and the state. The physician might educate the state as to why he was prescribing a non-preferred medication, which could be reviewed by the committee at a later date.

DAVID CAMPANA CALLED FOR A VOTE ON THE QUESTION OF WHETHER THE DRUGS ON THE LIST WERE THERAPEUTICALLY EQUIVALENT.

Ayes: Boothe, Brainerd, Brodsky, Carlson, Conright, Gale, Hampton, Hansen, Hopson, Liljegren, Miller, Polston, Reem, Stables, Stransky, White.
Nays: Babb, Skala.

The committee discussed which drugs should be on the PDL. Richard Reem felt they should have two drugs on the list, one that was renally metabolized and one that was emphatically metabolized. Richard Brodsky did not feel the information supported the concept that it was important that the drug be renally metabolized. Terry Babb said he would like to see Losartan eliminated from the list, because other drugs within the class had been shown to be as effective when given only once a day. Heidi Brainerd felt Losartan had an advantage in diabetic nephropathy, although she understood the dosage interval was a concern.

Sandy Kapur pointed out that the committee had come to the conclusion that although not completely interchangeable, the drugs were relatively similar. Diovan, Diovan HCT, Teveten, Teveten HCT, Benicar, and Benicar HCT were recommended as being the most clinically and cost effective. Cozaar and Avapro are the only two agents approved for diabetic nephropathy, but there were ongoing trials for Diovan and Teveten. It was her understanding that all ARBs were subject to prior authorization per the VA contract. A patient must be intolerant to ACE Inhibitors before the VA approved ARBs. Diovan, Teveten and Benicar were the most cost-effective agents per First Health and were on Michigan's and Vermont's PDL.

In response to Robert Skala, Sandy Kapur there was a significant price difference between Diovan, Teveten and Benicar and the other drugs. Diovan, Teveten and Benicar, as a bundled package, provided the net best cost as well as leverage from the other states.

Sandy Kapur said the pricing of the drugs was based on the bundled package. Choosing only one of those drugs would decrease the cost savings. Diovan, Teveten and Benicar were made by different manufacturers. Choosing these three drugs would put Alaska on the same tier level as other states, which would increase the state's rebates and buying power.

TERRY BABB MOVED TO ACCEPT DIOVAN, TEVETEN AND BENICAR AS THE PREFERRED AGENTS FOR THE ALASKA PREFERRED DRUG LIST. SECONDED BY GEORGE STRANSKY. DAVE CAMPANA CALLED FOR A VOTE ON THE MOTION.

Ayes: Babb, Boothe, Brodsky, Carlson, Conright, Gale, Hampton, Hansen, Hopson, Liljegren, Miller, Polston, Reem, Skala, Stables, Stransky, White.
Nays: Brainerd.

In response to Ronald Miller, Heidi Brainerd said she voted against accepting the three drugs due to the diabetic nephropathy indications.

V. Angiotensin Converting Enzyme Inhibitors (ACEI's)

Sandy Kapur said there were ten available ACEI Inhibitors on the market. The four available as generics were Captopril, Enalapril Maleate, Lisinopril and Moexipril HCL. The remaining six agents, Monopril, Lotensin, Accupril, Aceon, Mavik and Altace were available single source, but Monopril, Lotensin and Accupril were pending generic manufacture pending litigation. All agents, except Mavik, Aceon and Altace, were available with hydrochlorathiazide. Lotensin is available as a combination product Lotrel. Mavik is available as a combination product Tarka. Vasotec is available as a combination product Lexxel. In regards to diabetic nephropathy, Captopril is the only ACE Inhibitor with the indication for the treatment of diabetic nephropathy in type 1 patients. However, the ADA specifies that any ACE Inhibitor could be used. ACE intolerant patients may be switched safely to an ARB. From the recent ACC and AHA guidelines for the evaluation and management of chronic heart failure in adults, ACE Inhibitors are recommended unless there are contraindications for side agents in patients with heart failure and post-MI patients with systolic dysfunction. An excerpt in the package state that most of the evidence supporting effective ACE Inhibitors on the survival of patients with heart failure is derived from experience with Analopril. Available data suggests that there are no differences among the available ACE Inhibitors in their effects on symptoms for survival. Some have suggested that the drugs in this class may differ in their ability to inhibit tissue ACE, however Notral has actually shown that tissue ACE Inhibitors are superior to other ACE Inhibitors in any clinical aspect of HF. In selecting among ACE Inhibitors, it is recommended to give preference to ACE Inhibitors that have shown to reduce morbidity and mortality. The HOPE trial gave Altace the unique indication of reducing risk of MI, stroke, death and death from cardiovascular causes in patients 55 years of age or older at a high risk for developing cardiovascular events because of coronary artery disease, stroke, peripheral vascular disease or diabetes. In animals it has been shown that Quinapril and Lotensin have the highest tissue ACE binding affinity, followed by Altace, Aceon, Lisinopril, Enalapril, Monopril and Captopril. There are differences in the PK and PD between the ACE Inhibitors, however this has not been shown to be clinically significant. The EUROPA trial was Aceon 8 milligrams against placebo and studied the ability of Aceon to reduce the risk of cardiovascular death, myocardial infraction and cardiac arrest in

patients with stable CHD without heart failure or substantial hypertension. The trial was similar to HOPE, but different in that EUROPA included patients who were at low risk for CV complications and with a third of the patients being less than 55 years of age. The HOPE trial patients were at a higher risk for CV complications with more patients who had diabetes, hypertension, stroke and peripheral vascular disease, which translate into a higher percentage of patients with total mortality, CV mortality and Q wave MI than that of the EUROPA study. EUROPA concluded that Aceon significantly improved CV outcomes in patients at low risk for CV disease and those with stable CHD without heart failure. Aceon reduced the primary end point of CV death, MI and cardiac arrest by 20%, reduced fatal and non-fatal MI by $24 and reduced hospitalization for heart failure by $39. The JNC-VII guidelines on hypertension said patients with systolic blood pressure, diastolic blood pressure greater than 20 over 10 for their goal in hypertension should be implemented on two agents. Unless there is a contraindication, one should be thiazide diuretic. We only proposed combinations that had a thiazide diuretic. In African American patients, it is stated that patients with a systolic blood pressure of 15 millimeters or mercury over 10 millimeters greater than goal should be implemented on combination therapy with a thiazide diuretic being one of those agents. A unique feature with Mavik is it has a special dosage indication for African Americans, but it does not have any claims in superiority over any other ACE Inhibitors for African Americans. It is a well-known fact that low renin producers, particularly African Americans, do not respond to ARBs or ACEs as well as the Caucasian population. That can be compensated for by increasing the dosage, adding a thiazide diuretic or adding another agent to bring it back to equivalency with the Caucasian population.

In response to Robert Skala's question on the demographics of the population, David Campana said he could provide that information at the next meeting. Generally, most of the people in Medicaid were between the ages of 40 and 60, with a few between 60 and 80. The gender was slanted towards females. The ethnicity was similar to the general Alaska population. He did not have the exact figures at the meeting, but the information was available in the 2003 annual report on the state website.

Sandy Kapur said the VA decided in their class review that they needed at least one long acting agent and one short acting agent. Captopril and Enalapril were given three times a day whereas the others were given once a day. The VA believes the ACI Inhibitors to be of a class effect, but they allowed for provisions for physicians who believed otherwise through a prior authorization for Altace.

The committee discussed which drugs should be added to the PDL for ACE Inhibitors. Sandy Kapur suggested dividing the ACE Inhibitors into those with high tissue ACE binding affinity and those without high tissue ACE binding affinity. Quinapril and Lotensin were equal, followed by Altace, Aceon, Prinivil, Vasotec, Monopril and Capoten. Aceon has now been proven in a trial to be similar to Altace. Vasotec, Monopril, Altace and Mavik have an average trough-peak ration greater than 50% from data from published studies, thus fulfilling the FDA recommendation that once daily formulations have a trough-peak ratio of greater than 50%. According to FDA labeling, all ACE Inhibitors, with the exception of Captopril, can be considered once daily.

The committee further discussed which drugs should be on the PLD. Richard Brodsky felt there was some rationale to include Captopril on the list. Robert Skala felt they should look at the drug's effectiveness compared to its cost. David Campana suggested looking at the recommendations and the costs. Terry Babb felt strongly that Ramipril should be included on the PDL, because it was his understanding that the tissue ACE binding affinity was nothing more than an theory to explain away a class effect. David Campana noted that a drug that had passed its exclusivity period and was generic would be on the list, so Captopril, Enalapril and Lisinopril would be on the PDL.

TERRY BABB MOVED TO INCLUDE ALTACE ON THE PDL. SECONDED BY UNIDENTIFIED MALE. DAVID CAMPANA CALLED FOR A VOTE ON THE MOTION.

Ayes: Babb, Boothe, Brainerd, Brodsky, Carlson, Conright, Gale, Hampton, Hansen, Hopson, Liljegren, Miller, Polston, Reem, Skala, Stables, Stransky, White.
Nays: None.

David Campana asked the committee to decide if the drugs, except Captopril and Altace, were interchangeable. The generic drugs would automatically be included on the PDL. Sandy Kapur said the exception to the generic drugs was Moexipril, because it was still more cost effective to use the brand name drug. The committee had the ability to place only the generic drugs on the PDL, which Michigan did for this class. Vermont and Michigan did not include Altace. Terry Babb felt they needed to vote to put the generic on the PDL and not just assume that they would be included.

In response to Terry Babb's question, Sandy Kapur did not know if Monopril had an active metabolite. Terry Babb said Monopril did not have dosage adjustments for the elderly with renal impairment potential and may or may not be a safety issue. Sandy Kapur said the dosage of the other agents could be increased for renal impairments.

UNIDENTIFIED MALE MOVED THAT THE ACE INHIBITORS, EXCLUDING CAPTOPRIL AND ALTACE, WERE INTERCHANGEABLE. SECONDED BY UNIDENTIFIED MALE. DAVID CAMPANA CALLED FOR A VOTE ON THE MOTION.

Ayes: Boothe, Brainerd, Brodsky, Carlson, Conright, Gale, Hampton, Hansen, Hopson, Liljegren, Miller, Polston, Reem, Skala, Stables, Stransky, White.
Nays: None.
Abstain: Babb.

Sandy Kapur said they recommended Aceon, Captopril, Enalapril, Lisinopril, Lotensin, Mavik and Univasc. The generic of Univasc was not preferred. The combination products include Captopril HCL, Enalapril HCL, Lisinopril HCL, Lotensin HCL and Univasc HCL, but none of the combination products with the dihydropuridine (ph) or non-dihydorpuridine (ph) calcium channel blockers.

In response to Heidi Brainerd, Sandy Kapur said Michigan decided only to cover the generic drugs, because their cardiologist believed that all the ACE Inhibitors were equivalent.

Heidi Brainerd suggested covering only the generics for this class, with the exception of Altace. Sandy Kapur said that would significantly decrease the cost savings, because physicians would lean towards prescribing the brand name product, Altace. Terry Babb did not feel physicians would prescribe Altace just because it was on the list. Most physicians prescribed Enalapril or Prinivil.

In response to Heidi Brainerd, David Campana said the committee could revisit the PDL list in three months if one medication was being prescribed more than they felt it should be or if new information came out. The edits would not begin until January 1, 2004, so the first review would be in March.

The committee discussed how the drugs on the PDL would be prescribed. David Campana said a drug could be prescribed as medically necessary, because the patient fit the HOPE trial criteria. Heidi

Brainerd was concerned about having an indication for a certain trial, because as new trials were published the criteria would have to be revised. Sandy Kapur pointed out that the choice of which drugs to prescribe was at the physician's discretion and he would just write "medically necessary per X trial." Robert Skala felt they needed to make a commitment to their patients on which drugs were best. Heidi Brainerd suggested leaving certain drugs on the PDL, but requiring a few extra steps to authorize them.

David Campana summarized the discussion. The PDL would contain the generics plus Altace. The physician will not have to specifically indicate Altace at this point, but they would review the issue if Altace was being over prescribed.

UNIDENTIFIED MALE MOVED TO INCLUDE ALL OF THE GENERIC ACE INHIBOTORS, PLUS ALTACE, ON THE PDL. SECONDED BY AN UNIDENTIFIED MALE. DAVID CAMPANA CALLED FOR A VOTE ON THE MOTION.

Ayes: Babb, Boothe, Brainerd, Brodsky, Carlson, Conright, Gale, Hampton, Hansen, Hopson, Liljegren, Miller, Polston, Reem, Skala, Stables, Stransky, White.
Nays: None.

Ronald Miller noted that Sandy Kapur said Univasc was cheaper than the generic drug. Sandy Kapur suggested doing a separate cost analysis for the different proposals, all generics plus Altace; all generics plus the recommended agents and Altace; and all of the recommended agents; which could be reviewed at the next meeting before making a final decision. Adding Altace would significantly increase the price, however, adding the recommended agents and Altace may be less than just keeping Altace and the generics.

David Campana said net prices had been negotiated for certain packages of drugs, which might be better than the generic drugs. With the rebates, sometimes the name brand drug is more cost effective to Medicaid than the generic. We receive 15.7% of average manufacture price for the brand name drugs, but we only get 11% for the generic. He explained how that related to the end price of the drugs.

Ronald Miller suggested tabling the final decision until the cost analysis could be provided. He felt this information should be available for future meetings while they discussed the specific classes.

In response to Heidi Brainerd, Sandy Kapur said the contract prices were good for three years after the list was publicly posted on the website.

Richard Reem pointed out that the committee was supposed to come to an independent decision on the PDL, regardless of what other states had done. Richard Brodsky said they had not come to the decision that the generics were the best. With the information they had, it seemed the generics would be the cheapest alternative and the best advantage of the state. It would be to our advantage to pool with as many states as possible to get the lowest pricing.

David Campana said it was their intent to go forward with a public process to determine whether there were class effects or if the drugs were interchangeable. Richard Brodsky pointed out that the committee had determined that the drugs were equivalent, except for Captopril and Altace. The final decision would be based on the price of the remaining drugs. Sandy Kapur said they would present the most cost-effective drugs at the next meeting. Arthur Hansen asked to have that information provided at all

further meetings. David Campana said the PDL would include all the generics, plus Altace, until they received a more definitive answer on the costs of the remaining drugs.

In response to an unidentified male, Sandy Kapur said she could provide the committee with market share information, but she felt that might skew their opinion. They have seen dramatic market share shifts, because P&T Committees in other states have decided these classes were universal. Terry Babb felt the market share information should be available. The committee accepted First Health's recommendations and there should be information on the impact of that decision. Robert Skala felt they needed to know if the implemented changes would actually produce a cost savings or if they were making the same decisions that were already in place. Terry Babb said by completing the first two drug classifications, they must have some idea of what the financial impact would be on the Medicaid system. An unidentified male said he wanted to know what percent of people that would be prescribed ARBs in Alaska were now on a medication that was not on the PDL. Given that they had followed First Health's recommendations, he felt that information should be available. Janice Stables said at the first meeting they had been told that they would sit together as clinicians and review the drugs for their effectiveness and decide what would work for Alaskans before considering the costs. Eventually, Medicaid would have to provide the committee with reports on the effectiveness of this project.

In response to an unidentified male, David Campana said the generic drugs, except for Monopril, plus Altace, had been chosen. The committee would revisit the decision next month at which time the decision could be amended.

VI. Proton Pump Inhibitors

Sandy Kapur said there were currently seven agents on the market, Aciphex, Nexium, Prilosec, Protonix, Omeprazole and Prilosec OTC. Although there are seven agents to choose from, they only represent four distinct chemical compounds, Aciphex, Prevacid, Protonix and Nexium. Each of the agents have been shown to apply in clinical trials in the healing and maintenance of erosive esophagitis and symptomatic treatment of GERD. There are some subtle differences that may help to differentiate the products. Food affects on the agents are one area where there is a difference. The product labeling of Prevacid reports a 50% in AUC if taken with food. The Nexium label reports a 33% to 53% decrease in AUC if taken with food. Protonix, in clinical trials, just before, during and after the first major meal of the day showed no decrease in AUC or CMAX. For that reason, the Protonix label reads that the drug can be administered without regards to food. The AGA consensus statement from September 2, 2002 stated that there was no clinical evidence to support differences between available PPIs for treatment of endoscopy-negative GERD. Nexium has been inconsistently found to have higher esophagitis healing rates that Prilosec and Prilosec, however the clinical significance of this has not been substantiated. They stated in their guidelines that in light of comparable safety and efficacy, cost may be a factor in choosing PPIs. The five FDA approved PPIs are all very potent acid suppressing agents. Studies actually show minimal differences between the PPIs and secondary end points of any vetra PH and acid suppression. In head-to-head comparisons, PPIs are very similar in effectiveness for both GERD and healing esophagitis. The conclusions from the VA said the PPIs may be considered for therapeutic interchange because of their comparable pharmacological properties and clinical efficacy and safety profiles. Consistent results of clinical trails in patients with duodenal ulcers, gastric ulcers, GERD, hypersecretory conditions and other acid-related disorders strongly suggest that there is a class effect of PPIs for these disorders, although differences in dosage formulations and drug interactions may occasionally influence choice of PPI in individual cases. The only agent that has FDA labeled pediatric indication is Prevacid. Prilosec is the most well studied agent and the North American Gastric Society

of Children stated that Prevacid and Prilosec may be used in the pediatric population. There are also unpublished studies for Protonix.

RICHARD BRODSKY MOVED THAT ALL THE PPIs WERE INTERCHANGEABLE AND EQUIVALENT. SECONDED BY AN HEIDI BRAINERD. DAVID CAMPANA CALLED FOR A VOTE ON THE MOTION.

Ayes: Babb, Boothe, Brainerd, Brodsky, Carlson, Conright, Gale, Hampton, Hansen, Hopson, Liljegren, Miller, Polston, Reem, Skala, Stables, Stransky, White.
Nays: Unidentified female.

(Note: An unidentified female was opposed due to the pediatric indications.)

David Campana said the committee could say that children were exempt from this.

The committee discussed which drugs should be on the PDL. An unidentified female felt they needed something with pediatric indications. Another unidentified female felt they needed something with a criteria for nursing homes. (Indiscernible -- multiple speakers away from the microphone.)

David Campana questioned if the committee wanted an exception process for children. They could build edits that allowed for Prevacid and Omeprazole. George Stransky felt they needed to review the cost effectiveness of the drugs before making a decision on exceptions. Terry Babb questioned if anyone was concerned about the potential for drug interactions that only Omeprazole had or the non-availability of IV formulations. Sandy Kapur said all of the drugs discussed only related to the oral formulations. The IV formulations were always exempt. First Health recommended Protonix, but exemptions and provisions could be made for pediatrics and long-term care. The only generic available is Omeprazole, which is available over the counter. In their recommendations, they put Prilosec OTC and the generic Omeprazole on the non-preferred side.

The committee discussed how the exceptions would work. Sandy Kapur said the exception could be done automatically for children. If they did the exception systematically for long-term care, even patients who could take oral formulations would be allowed to get the Prevacid. They recommended for long-term care that the physician would note on the prescription that the patient could not swallow.

AN UNIDENTIFIED MALE MOVED TO PLACE PROTONIX ON THE PDL, WITH AN EXCEPTION FOR THOSE UNDER 12 YEARS OF AGE FOR PREVACID. SECONDED BY AN UNIDENTIFIED MALE. DAVID CAMPANA CALLED FOR A VOTE ON THE MOTION.

Ayes: Babb, Boothe, Brainerd, Brodsky, Carlson, Conright, Gale, Hampton, Hansen, Hopson, Liljegren, Miller, Polston, Reem, Skala, Stables, Stransky, White.
Nays: None.

An unidentified male requested that the committee take up Histamine H2 Receptor Antagonists H2Rs next.

VII. Histamine H2 Receptor Antagonists H2RAs

Sandy Kapur said there were H2RAs, Zantac, Axid, Tagament and Pepcid. They were all available generically except for the liquid formulation of Zantac, Pepcid and Zantac Tablet EFF. All have been shown to be efficacious in the treatment of GERD and mild to moderate esophagitis. Efficacy improves at higher and more frequent doses. Few differences have been seen, but more than likely this is due to various study designs and/or inclusion criteria. The small differences found in the individual studies are not likely to have a clinical impact in the selection of H2RAs when you take into consideration the entire body of literature published. The major differences between these agents are side effects and drug interaction profiles and the tolerability to Tagament for cimetidine, which also has antiandrogenic effects.

In response to Heidi Brainerd's question on pediatric indications, Sandy Kapur said Pepcid and Zantac were the only liquids. Pepcid has to be refrigerated and discarded after 30 days. The Zantac liquid is the preferred agent due to its ease in dosing and hydration ability in the pediatric population. The committee could make exceptions for the Pepcid and Zantac liquids as deemed necessary.

The committee discussed which drugs should be on the PDL. Kelly Conright felt there needed to be another option available, besides Zantac, for the elderly, because they tend to avoid Zantac due to the possibility of delirium and drug interactions.

Sandy Kapur said they recommended the generics Famotidine and Ranitidine. They did not recommend the generic of Tagament, Axid or Nizatidine for pricing purposes.

UNIDENTIFIED MALE MOVED THAT THE DRUGS WITHIN THE CLASS WERE INTERCHANGEABLE AND FAMOTIDINE AND RANITIDINE SHOULD BE ADDED TO THE PDL. SECONDED BY UNIDENTIFIED MALE. DAVID CAMPANA CALLED FOR A VOTE ON THE MOTION.

Ayes: Babb, Boothe, Brainerd, Brodsky, Carlson, Conright, Gale, Hampton, Hansen, Hopson, Liljegren, Miller, Polston, Reem, Skala, Stables, Stransky, White.
Nays: None.

VIII. Bisphosphonates

Sandy Kapur said there were two bisphosphonates for osteoporosis, Actonel and Fosamax, although she included information on other agents in the materials for future reference. There are no head-to-head trials of Fosamax versus Actonel. The FACT trial, sponsored by Merck, will be the first stage of evaluating the drugs head-to-head. The American Association of Clinical Endocrinologists stated there is level one evidence of efficacy in reducing the risk of vertebral fractures for alendronate, risedronate, calcitonin and raloxifene. Calcitonin is in its own class. Raloxifene is the only agent available that is not included or excluded within the PDL and that class will not be discussed. There are efficacy studies for both Actonel and Fosamax that have been shown in primary prevention of vertical fractures, secondary prevention, primary prevention of hip fractures, secondary prevention of hip fractures and prevention of steroid induced vertebral fractures. The VA PDM stated Alendronate and risedronate produce similar results with regard to treatment and prevention of osteoporosis and treatment of steroid induced osteoporosis. Although prevention of steroid induced osteoporosis in treatment of men with primary osteoporosis has not been shown with one of the drugs, Actonel and Fosamax, this is believed to be a class effect and equivalent outcomes would be expected.

RICHARD BRODSKY MOVED THAT THERE WAS NO SIGNIFICANT DIFFERENCE BETWEEN ACTONEL AND FOSAMAX. SECONDED BY AN UNIDENTIFIED MALE. DAVID CAMPANA CALLED FOR A VOTE ON THE MOTION.

Ayes: Babb, Boothe, Brainerd, Brodsky, Carlson, Conright, Gale, Hampton, Hansen, Hopson, Liljegren, Miller, Polston, Reem, Skala, Stables, Stransky, White.
Nays: None.

Sandy Kapur said they recommended Actonel be added to the PDL. Actonel has been shown to have less GI upsets than Fosamax.

AN UNIDENTIFIED MALE MOVED TO ADD ACTONEL TO THE PDL. SECONDED BY AN UNIDENTIFIED MALE. DAVID CAMPANA CALLED FOR A VOTE ON THE MOTION.

Ayes: Babb, Boothe, Brainerd, Brodsky, Carlson, Conright, Gale, Hampton, Hansen, Hopson, Liljegren, Miller, Polston, Reem, Skala, Stables, Stransky, White.
Nays: None.

IX. Beta-Blockers

Richard Brodsky asked if they would consider the beta-blockers as a whole or individual subgroups. Sandy Kapur said she could discuss the subgroups, but the crux of the matter came down to the indication in the treatment of heart failure and the interchangeability of Betapace and Betapace AF, neither of which were recommended. They preferred the generic of Sotalol, because outside of color, dosage strength and the package labeling insert for Betapace AF, they considered those to be interchangeable. The only point of contention is the indication of the treatment of heart failure. The largest predominance of evidence are for three agents, extended release Metoprolol, Coreg and Visaprolol. Visaprolol is a little known agent, but was the first agent to show efficacy in the treatment of heart failure and is only available generically, but there is no one who will fight for it to get the FDA label indication in this country. In Europe, Australia and New Zealand, Visaprolol has the indication for heart failure and is a very well used agent. The MERIT HF studied was for Metoprolol XL. The COMET study was for immediate release Metoprolol versus Coreg. She did not feel anyone could say that Metoprolol XL versus Coreg was either better or worse than the other. The VA PBM questioned if in the treatment of hypertension whether they needed to go with a more expensive once daily treatment or a generic once daily treatment if the patient does not have heart failure or if they needed to have access to Coreg and Toprol XL for the treatment of heart failure.

Richard Brodsky said there was a strong statement from 90% of the cardiologists in Alaska that said Carvitolol was the preferred agent and he felt it should be on the PDL.

Sandy Kapur said for the combined alpha non-selective beta-1 agents there was Coreg, Trandate, and Normodyne, which is available generically as Lebetalol. They recommended the Lebetolol. For the beta-1 selective agents there is Sectral (available generically), Tenormin (available generically), Kerlone (not available generically), Zebeta (available generically), Lopressor (available generically), and Toprol XL (not available generically). Out of the beta-1 selective agents, they recommended the generic agents.

Richard Brodsky asked if the committee wanted to vote on each category separately to avoid confusion. Sandy Kapur said clinically and economically, the question came down to whether the committee wanted Coreg and Toprol XL, neither of the agents or only one of the agents.

The committee discussed which drugs they wanted on the PDL. In response to Richard Reem, Sandy Kapur said the beta 1 selectives, Atenolol, Visaprolol and Toprol, were kinder asthmatics.

ROBERT SKALA MOVED TO ADD COREG, TOPROL XL AND THE GENERICS, MINUS BETAPACE AF, TO THE PDL. SECONDED BY HEIDI BRAINERD.

Terry Babb questioned if the immediate release form of Metropolol should be included on the PDL. Sandy Kapur said there had been a comparison of immediate release Metropolol to extended release Toprol and the human dynamic parameters were identical. The MDC trial for immediate release Metropolol had negative outcomes for heart failure, but not for hypertension. Terry Babb felt there was a lot of value in medications that only had to be taken once a day by making it easier for patients. Sandy Kapur said she had read that patients were more in tune with their health and compliant with their therapy when they knew they had to take medications at certain intervals during the day. The committee further discussed the differences between the medications.

Ayes: Babb, Boothe, Brainerd, Brodsky, Carlson, Conright, Gale, Hampton, Hansen, Hopson, Liljegren, Miller, Polston, Reem, Skala, Stables, Stransky, White.
Nays: None.

David Campana said he was open to suggestions on how to conduct future meetings. They wanted the committee to be as effective as possible in providing the patients with the best care possible in the most cost effective way. He discussed the drug classes that would be reviewed at the next meeting, which would be posted on the website.

In response to Kelly Conright, David Campana said expert testimony would be accepted by specialists in the drug classes to be reviewed at the next meeting. He would contact any physicians that were referred to him by the committee to provide expert testimony. An unidentified male said Julian Nailer, ANMC, should be contacted for diabetes. Brian McMann should be contacted for hepatitis agents. Robert Werner, an ophthalmologist, should be contacted.

David Campana said the next meeting would be December 19, 2003.

Kelly Conright asked if something could be done with the telephone system, which was inadequate for the meetings. David Campana suggested using a cell phone and passing it around to the members as they had questions. He would look into the telephone system prior to the next meeting. Starting in January, the meetings would be held in the Frontier Building, which was a better facility.

The meeting adjourned at 11:55 p.m.